

SECTION 3 TRAINING AND CERTIFICATION

INTRODUCTION

The purpose of training within WHI is to teach staff the WHI protocol and procedures for implementation at the Clinical Centers (CCs). The CCC conducted initial training sessions for all lead staff positions at the time of CC start-up. Replacement lead staff training's are held approximately every six months, as needed. In addition, national meetings may include training-like sessions for appropriate CC staff. CC lead staff are responsible for training CC non-lead staff.

Initial certification and regular recertification ensures that staff have a general understanding of the study procedures, have mastered an acceptable performance standard, and have maintained their skills. Lead staff and all other CC staff responsible for data collection or performing specific WHI procedures must be initially certified for the specific tasks they perform and recertified annually. In general, the certification process asks that staff members read relevant WHI documents and show they can perform the specific tasks according to predefined guidelines. Recertification ensures that their knowledge and skills are kept current.

This section describes:

- Training and certification resource materials available,
- Training requirements, and
- Procedures for documenting certification and recertification.

3.1 Resource Materials

The CCC has developed various training and certification materials for CC-specific procedures. To address the differences in CC staffing patterns and responsibilities, the training materials are primarily task-specific, rather than job description specific. Copies of the materials are included in the appendices of this manual and in the electronic files (see *Sec. 2.3 - Electronic Files*).

- **Certification Forms:** These forms list required and/or recommended steps in the training process for each specific task (see *Appendix B - Certification Forms*). The Certification Forms are designed to be used for both initial certification and annual recertification, with a new form completed for each annual recertification. Dashes to the left of the activities indicate which activities need to be completed for initial annual certification, and provide a place to mark those activities completed. All the certification forms list WHI Manual reading and review requirements. In general, staff are required to read the listed manual sections for initial certification, and to review the same section as a reminder of the current procedures and to note any changes for annual recertification.

A General Certification Form (*Form 400*) lists the general reading requirements for all CC staff, including the protocol and manual sections providing a general WHI description. Specific lead staff certification forms have been developed that summarize all tasks that fall under each of the lead staff positions. See *Table 3.1 - Training and Certification Resource Materials* for specific activities for each lead staff group. Also refer to *Vol. 2, Section 2.4 - Staffing* for a description of the general responsibilities for each lead staff group

- **Training/Quality Assurance (QA) Checklists:** Training/QA Checklists contain step-by-step procedures for performing specific tasks (see *Appendix C - Training/Quality Assurance Checklists*). Each checklist includes columns to indicate if the listed task was observed and to record comments. The forms were designed to be completed by an observer while the staff person being evaluated performs the specific task. The Training/QA Checklists are used during:
 - Training, certification, and recertification,
 - Peer observations for routine monitoring, and
 - QA visits to the CCs, with the completed checklists becoming a part of the QA Visit Report.

Note that there is a corresponding training/QA checklist for each certification form; however, there are no training/QA checklists for the lead staff certification forms. Instead, the checklists lead staff are required to complete are incorporated into the lead staff certification forms. Note also that there are additional training/QA checklists for tasks which do not require certification, but which can assist in training. These additional checklists are included on the appropriate lead staff certification forms.

- **Videos:** Standard VHS videotapes supplement training in specific areas, such as endometrial aspirations or ECGs. Contact the CCC Training Coordinator about training tapes that are currently available.
- **Nutrition Training Modules:** Training Modules are available for selected DM activities. Included are 9 modules for use in training Group Nutritionist and Dietary Assessment staff. Each module includes performance objectives, a list of materials, training activities, and a suggested timeframe. Group Nutritionists and Dietary Assessment (DA) staff must be trained by the Lead Nutritionist who has been centrally trained and certified by the CCC. If a CC has a split Lead Nutritionist position, the Lead DM Interventionist must train and certify Group Nutritionist staff and the Lead DA Nutritionist must train and certify DA staff. The modules and related materials are included in the set of electronic files. See *Section 2.3 - Electronic Files*.
- **Training Outlines:** Outlines used for conducting lead staff training sessions are available in the set of electronic files. See *Section 2.3 - Electronic Files* for a list and copy of those available.

Table 3.1 - Training and Certification Resource Materials lists the training and certification materials available. For each listed CC activity, the table shows the Certification Form and Training/QA Checklist

numbers. All Certification Forms and Training/QA Checklists have been renumbered, with Certification Forms numbered 400-499 and all Training/QA Checklists numbered 500-599. Where possible, the Certification and Training/QA Checklist form numbers use the same last two digits. For example, the Certification Form number for ECG is 441 and the corresponding Training/QA Checklist is numbered 541. The table also lists the previous Certification and Checklist numbers for reference. Other sections of the WHI Manuals referring to these forms will be updated as part of normal manual updates.

The table lists the activities in following categories: Lead Staff positions, Consent and Participation Status, Clinical, Nutrition, Outcomes, Data Management and Clinic Operations. For each activity, the table gives the following information:

- Clinical Center Activity: Name of activity requiring certification or for which a Training/QA checklist is available.
- Certification Form Number: A Certification Form number is listed for only those activities requiring certification. Staff do not need to be certified for the listed activities that do not have a corresponding Certification Form number.
- Training/QA Checklist Number: Number of the corresponding checklist.
- WHI Form Numbers: Indicates the WHI forms covered in the Certification Forms and Training/QA Checklists.
- Lead Staff Training Responsibilities: Columns for the lead staff groups indicate the activities covered in the lead staff training's. Lead staff are responsible for the initial training, certification and recertification of non-lead staff on the indicated activities.

Table 3-1
Training and Certification Resource Materials

CC Activities	Certification Form #	Old #	Train/QA Checklist #	Old #	WHI Form # (WHILMA Task #)	Lead Staff Training Responsibilities						
						CM	RC	LP	LN	DC	OCS	
									DM	DA		
General Certification	400	-	-	-		X	X	X	X	X	X	X
Lead Staff Positions												
Clinic Manager (CM)	401	201	-	-		X						
Recruitment Coordinator (RC)	402	202	-	-			X					
Lead Practitioner (LP)	403	209	-					X				
Lead Nutritionist (LN)			-									
Lead DM Interventionist (DM)	404	-		-					X			
Lead Dietary Assessment Nutrit. (DA)	405	-	-	-						X		
Data Coordinator (DC)	406	221	-	-							X	
Outcomes Specialists (OCS)	407	-	-	-								X
Consent and Participant Status												
Initial Consent	411	206	511	301	11	X	X	X				
HRT Consent	411	206	512	302	12	X		X				
DM Consent	413	224	513	339	13				X	X		
OS Consent	411	206	514	351	14	X		X				
CaD Consent	411	206	515	352	15	X		X				
DM/HRT Eligibility and Randomization	416	-	516	348	6,8,(910)(920)	X		X	X	X	X	
CaD Eligibility and Randomization	416	-	517	347	8, 16,(930)	X		X			X	
OS Eligibility and Enrollment	416	-	518	346	8, (940)	X		X			X	
Participation Status and Retention	419	-	519	-	7,22,23,24	X		X	X	X	X	
Clinical												
Study Medication Handling	-	-	530	315		X					X	
Study Medication Dispensing	431	-	531	340				X				
Study Medication Adherence Collection	432		532	341				X				
Data Entry for Study Med Selection and Adherence Collection	433	208	533	349	(950),(951),(955)						X	
HRT and CaD Management and Safety Interview	434	233	534	323	10,17,54			X				
Unblinding	-	-	535	344							X	

	Certification Form #	Old #	Train/QA Checklist	Old #	WHI Form # (WHILMA Task #)	Lead Staff Training Responsibilities					
CC Activities						CM	RC	LP	LN	DC	OCS
									DM	DA	
Lab Review	440	230	540	343	81, 82,83, 85, 92, 100			X			
ECG	441	214	541	311	86, 91			X			
Breast Exam	442	229	542	309	84, 89			X			
Pelvic Exam & Pap Smear	443	228	543	310	81, 92			X			
Endometrial Aspiration	444	227	544	316	82, 83			X			
Blood Drawing, Urine Collection	450	215	550	312	100, 101			X			
Blood and Urine Processing	451	213	551	313	100, 101			X			
Blood and Urine Shipment	-	-	552	314	104	X					
Anthropometric Measurements	453	211	553	307	80			X			
Pulse & Blood Pressure	453	211	554	306	80			X			
Functional Status Measurements	453	211	555	317	90			X			
Nutrition											
DM Intervention (a,b,c)	-	218	560A,B,C	305a, b,c					X		
DM Session Observation	461	219	561	336	63,64,65,70,71,72				X		
DM Eligibility	462	225	562	338	6,11,62				X	X	
DM Post-Randomization Interview	463	226	563	337					X	X	
Dietary Assessment (a,b,c)	-	218A	564A,B,C	328a,						X	
Food Frequency Questionnaire	465	220B	565	330	60, 61					X	
Food Record Instruction	466	220A	566	331	62, 69					X	
Food Record Documentation	466	220A	567	329	62					X	
Outcomes											
Outcomes	470	-	570	354	33,33D, 120s					X	X
Participant Files	-	-	581	332	all	X				X	
Data Management											
Data Entry and Scanning	480	222	580	327	all					X	
Participant Files	-	-	581	332	all	X				X	
Participant File Audit (Off Site)	-	-	582	326		X				X	
Participant File Audit (On Site)	-	-	583	333		X				X	

						CM	RC	LP	LN		DC	OCS
									DM	DA		
Clinic Operations												
Interviewing and Forms Review	490	205	590	300	2,3,4,20,30,31,32,34,35, 37,38,39,42,43,(44),(45), 48,143,144,145	X	X	X		X	X	X
Screening Visit	-	-	592	318	-	X						
Follow-up Visit	-	-	593	319	-	X						
OS Follow-up	-	-	594	353	-	X						

3.2 CC Staff Training Requirements (Required)

Required training activities are defined for all CC lead and non-lead staff. The CCC conducts central training for all lead staff. Supplemental training sessions may also be offered on regular staff group calls. In addition, national meetings may also include training-like sessions for appropriate CC staff. Some CC lead staff may have responsibilities for more than one staff group area, and therefore need to attend more than one central training session. Trained CC lead staff, in turn, conduct training for non-lead staff.

3.2.1 Initial Lead Staff Training (Required)

Clinical Center lead staff were required to attend initial central training sessions at the time of CC start-up before clinic activities began. Topics covered in the initial training sessions corresponded to the general areas of responsibility for each of the lead staff groups. (See *Vol. 2 - Procedures, Section 2.4 - Staffing.*) The Bone Density Center at UCSF ensures Hologic training of CC staff performing bone densitometry at the three Bone Density CCs.

3.2.2 Replacement Lead Staff Training (Required)

Training sessions for CC replacement lead staff occur at the CCC approximately every six months, if needed. This allows newly hired CC Lead staff to attend central training within six months of hire. Lead staff who are hired after the initial training sessions or who become lead staff during the course of the study must attend the appropriate replacement training sessions. Because the number of staff attending a replacement training session is relatively small, the training sessions are usually completed in 2 to 3 days.

The content and materials covered in replacement sessions are similar to those covered at the initial training sessions, covering all activities that fall within the lead staff group responsibilities. After the training session for some lead staff groups, some additional training activities must take place at the CC for some tasks. The Certification Forms indicate the additional activities needed; these include activities such as observations by a consulting gynecologist of clinical exams, observations of DM Intervention sessions, and completion of practice ECGs.

3.2.3 Non-lead Staff Training (Required)

Clinical Center lead staff are responsible for training non-lead staff on appropriate procedures at the CC. At the discretion of the CC, non-lead staff may attend the CCC lead staff training sessions if the additional staff can be accommodated within the size limitations of the training session.

Clinical Centers are strongly encouraged to send at least one Group Nutritionist with the Lead DM Intervention Nutritionist to lead nutrition staff central training sessions. Any Group Nutritionists who cannot attend the central training sessions must be trained using the standard training and certification materials.

A clinic practitioner who performs clinical exams such as pelvic exams and endometrial aspirations needs to have observations and review by the CC consulting gynecologist.

3.2.4 Physician Adjudicators (Required)

The CCC and the Morbidity and Mortality Committee have developed sessions for a physician training plan in event adjudication for WHI. Physician adjudicators are trained by reading the appropriate sections of *Vol. 8 - Outcomes*, and participating in CCC activities for ensuring standardization of adjudication, for example, review of mock packets, conference calls, and case review meetings at regional CC meetings (see *Vol. 8 - Outcomes* for more details).

3.2.5 Consulting Gynecologists (Required)

Clinical Center PIs designate a consulting gynecologist for their CC. The consulting gynecologists do not participate in a formal training and certification process. Instead, they should review the relevant sections of the WHI Manuals and the Consulting Gynecologist Handbook. The Handbook contains information targeted for the consulting gynecologist, including the consulting gynecologist's role and responsibilities, copies of the pertinent WHI Manual sections, as well as samples of the forms and materials consulting gynecologists may need to fulfill their duties, are found in the handbook.

3.2.6 Conference Calls with Training Focus (Required)

Clinical Coordinating Center staff cover new or revised procedures on routine Regional Staff Group conference calls, as needed. If additional time is needed to cover specific topics or to include specific staff performing the activities, separate conference calls may be scheduled.

3.2.7 Annual General Meetings (Required)

Annual General Meetings are scheduled to occur every year, and the Steering Committee may select a lead staff group to attend, as needed. The meeting agenda is developed to include sessions for the selected lead staff group, based on study phase and training needs. These sessions target:

- Issues and concerns raised during the previous year or anticipated for the next year,
- Study requirements for the upcoming year,
- Adherence and retention issues, and
- Updated information as needed.

Lead staff groups can provide recommendations and rationale for sessions to the CC Staff Committee, which in turn provides the Steering Committee with specific recommendations.

3.3 CC Staff Certification (Required)

Certification is the process of documenting that a CC staff person has received adequate training and can perform a task consistent with study-wide criteria. Clinical Centers are responsible for ensuring all CC staff are appropriately certified for the WHI tasks they perform and that CC staff are recertified annually for these tasks. The CCC is responsible for reviewing the certification documentation at routine QA Visits.

To document the certification or recertification, a CC staff person must:

- Complete the required reading in the General Certification Form.
- Complete the required reading listed on the specific Certification Form. This includes review and reading of relevant task-specific sections in the WHI Manuals, relevant forms and/or use of WHILMA, as needed.
- Read relevant Bulletins. Staff need to read relevant Bulletins to ensure they are informed of most up-to-date procedures and policies. A table listing the relevant Bulletins is included in the Public Folders (see *Section. 2.3 – Public Folders* for description and information on access to the Public Folders). The table includes the certification task number and the references to pertinent parts of related Bulletins released in the past year.
- Observe and practice the specific task, guided by the corresponding Training/QA Checklist. Ideally, lead staff complete certifications and checklists on non-lead staff. Certified non-lead staff may complete the Training/QA Checklists on other staff if lead staff are not available to perform these observations. In addition, staff members may complete the checklists by themselves if other staff are not available to make the observations. However, observations by lead staff is strongly encouraged, particularly in those activities that involve interactions with participants.
- Complete other required activities listed on the appropriate Certification Form. Activities required for certification and recertification can differ. For example, initial certification may require training activities that are not required for recertification. Each Certification Form indicates which activities need to be completed for initial certification and those to be completed for recertification.
- Complete the appropriate Certification Forms (General and lead staff/task-specific).

To help track staff certification, use a tracking form such as the form shown in *Table 3.2 - Model Certification Tracking Form*. For each task a staff member performs, record the following: initial certification date, due date(s) for annual recertification, and annual recertification completion date(s). The CCC will review the certification records during routine QA Visits.

3.3.1 Initial Certification (Required)

Lead Staff

Lead Staff must attend the CCC initial or replacement staff training sessions and complete activities listed on the lead staff Certification Forms to be initially certified. Considerations for lead staff initial certification include:

- Clinical Center lead staff who have not attended initial training must come to replacement staff training to be initially certified.
- If Clinical Center lead staff complete only part of the required activities at initial/replacement lead staff training, the remaining activities must be completed at the CC before lead staff can be certified. The certification forms indicate which activities must be completed.
- CC lead staff who have more than one area of responsibility (e.g., Clinic Manager and Recruitment Coordinator) must meet the required certification conditions for each area.

- WHI Clinic Practitioner certification for physicians, nurse practitioners, physician assistants, and registered nurses requires that they be appropriately licensed according to local, state, and federal regulations. Clinic Practitioners planning to perform pelvic exams, pap smears, endometrial aspirations, clinical breast exams, or breast self-exam instruction can perform only those procedures legally within the clinical scope of their licensed practice.
- Replacement lead staff or current lead staff who change responsibilities must meet lead staff or task-specific training requirements before they can be certified for their new responsibilities.

Non-Lead Staff

Non-lead staff who have contact with participants, complete data collection forms, or perform specific tasks must be certified. This can be done at the CC by appropriate centrally trained lead staff or by other certified non-lead staff. Non-Lead staff are initially certified after completing the activities listed on the appropriate Certification Forms.

3.3.2 Recertification (Required)

Recertification (renewal of certification) is necessary to ensure ongoing standardization of protocols and procedures in the WHI. In general, staff can be recertified after completing activities for recertification listed on the appropriate Certification Forms.

Considerations for lead staff:

- Lead staff must be recertified in all areas covered by their lead staff responsibilities, even though they may not perform the specific activities at the CC. This will enable the lead staff to certify and recertify non-lead staff.
- In addition to annual recertification, Lead DM Intervention Nutritionists must maintain familiarity with the Dietary Modification (DM) Intervention session materials and experience with DM Intervention group skills. This expertise and experience is necessary to assure appropriate training and QA monitoring of CC Group Nutritionists. Recertification of Lead DM Intervention Nutritionists require that they:
 - Facilitate all the sessions of the **first** DM Intervention group begun at the CC.
 - Facilitate at least two ongoing DM Intervention groups. To increase flexibility and accommodate varying levels of availability, the DM Intervention Nutritionist can delay adding a second group until this first group has reached a monthly session schedule. This delay would spread out the intensity of the work required for group facilitation.
- Ideally, lead staff complete the training on QA checklists for non-lead staff. However, peer observations can be substituted for some observations. See *Section 3.3.1 – Initial Certification* above for more information. If there is no lead staff person who has been centrally trained to certify/recertify new non-lead CC staff, non-lead staff must still complete as much of the certification process as possible (example: CC is waiting to fill a lead staff position or replacement training won't occur for several months after a new lead staff person is hired). See *Section 3.3 – CC Staff Certification* for a list of activities to be completed. Observations by a centrally trained lead are not needed for several of the required tasks on this list (i.e., reading certification forms, manual sections, and relevant bulletins).

Considerations for non-lead Staff:

- Staff documenting *Form 62 - 4DFRs* must satisfactorily complete quarterly 4DFR exercises. The exercises are designed to enhance proficiency in documentation of the 4DFRs. The CCC develops the quarterly exercises based on recent study wide 4DFR Inquiries and distributes them to all Lead Dietary Assessment (DA) Nutritionists quarterly. The Lead DA nutritionist:
 - Copies the exercises and distributes them to appropriate staff to complete;

- Reviews and discusses the completed exercise with staff using the answer key and discussion guidelines provided with the exercise; and
- Documents the date of the discussion and files the completed exercises in a QA notebook for review at the next QA Visit.

3.3.3 CC Strategies for Certification/Recertification

The following strategies for certifying and/or recertifying staff arose from discussion on a series of routine Clinic Manager and Clinic Practitioner conference calls. The strategies listed below may assist CC staff in training lead and non-lead staff in an efficient and timely manner.

1. Use a group certification method so that multiple staff can be certified at the same time. For example, if specific bulletin changes need to be reviewed, this can be done in a group setting where questions, answers, and changes can be addressed.
2. Certify standard procedures in a group setting with mock scenarios for observations. This can accomplish several goals: certifies for multiple tasks (i.e., blood pressure and waist measurements), creates an opportunity for different scenarios to be presented and problem management to take place, and allows the staff to see the different perspectives that involve other staff members.
3. Have various staff members actually conduct a presentation to the rest of the staff on their responsibilities and their role in WHI. This presentation could cover materials that needed to be read and reviewed. This can encourage staff to work on their public speaking skills as well as give the entire staff an idea of what they do for WHI.
4. An alternative to the group certification method is to develop a checklist (with names of staff on the checklist) to list all reading material so appropriate staff could check it off next to their name after they have read anything that was distributed from the CCC.
5. Have staff check off all protocol changes in the bulletin as they are read. Another option is to review with appropriate staff a piece of the protocol monthly.
6. Provide an individual sign-off sheet for each procedural change that is implemented. A signature of a staff person would indicate she/he has read, been instructed, and if appropriate, was observed doing a new task and is responsible for seeing that it is implemented.
7. Create individual packets for each staff member that contain their respective checklists and reading materials. The packet is assembled and given to each staff person. When the staff person has completed the reading materials in the packet, she is expected to contact the certifier for observation of the task being done.
8. Have the most appropriate certified staff person recertify CC staff in specific tasks.
9. Use the month of December to certify/recertify CC staff as December is generally a slow month for scheduling participants.
10. Close down your CC for 1-2 days during the month of December, if possible for your CC, to certify/recertify.
11. Associate certification/recertification with annual performance evaluation so the two tasks are not separated.

Table 3.2
Model Certification Tracking Form

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Section 3 Training and Certification

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